Atty. Docket No.: BP0003-US IN THE UNITED STATES PATENT AND TRADEMARK OFFICE AND TRADEMARK O

oplication Serial No:

Date Filed:

Application Title:

Methods For Determining Organisms Not Requiring The

Separation Of Fixative Or Excess Probe

Applicants:

Rigby et al.

Group Art Unit:

1645

Examiner:

Sally A. Sakelaris

Certified Mail No.:

7099 3400 0007 5728 4760

Certificate of Mailing Pursuant to: 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail and addressed to: Commissioner for Patents, Washington, DC 20231 on this 10th day of March, 2003.

> Brian D. Gildea Reg. No. 39,995

Sir:

Information Disclosure Statement

In accordance with 37 C.F.R. §1.97, Applicant(s) hereby make of record the following information and publications, some of which have been identified in the International Search Report (copy attached). Copies of PTO Form 1449 and each publication listed thereon [INCLUDE REFERENCE CODE, E.G., (U.S. PATENTS: AA through AZ); (BA - BZ FOREIGN PATENTS) &/OR (CA - CZ JOURNAL ARTICLES ETC.)] accompany this statement, either in the entirety or in the relevant parts.

Fee

Since this correspondence is being mailed within 3 months of the filing date or because no Office Action on the merits has been received, it is believed that no fee is due for consideration of the documents contained herein. If however The Office determines that a fee is due for consideration of this Information Disclosure Statement, The Office is hereby authorized to deduct any other appropriate fee due from Deposit Account 02-3240.

Atty. Docket No.: BP0003-US

Customer Number/Correspondence Address

If not already done, please match this application with the customer number identified below.

Customer Number: 023544



23544

PATENT TRADEMARK OFFICE

[Insert Bar Code Here]

Respectfully submitted,

Date: Mail 10, 2003

Brian D. Gildea Reg. No. 39,995

Applied Biosystems 15 DeAngelo Drive Bedford, MA 01730 phone 781-280-2824 fax 781-280-2940

From the INTERNATIONAL SEARCHING AUTHORITY PCT BOSTON PROBES, INC. NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT. Attn. Gildea, Brian D. OR THE DECLARATION 15 DeAngelo Drive Bedford, MA 01730 UNITED STATES OF AMERICA (PCT Rule 44.1) Date of mailing (day/month/year) 14/02/2003 Applicant's or agent's file reference FOR FURTHER ACTION See paragraphs 1 and 4 below International application No. International filing date PCT/US 01/48675 (day/month/year) 14/12/2001 Applicant BOSTON PROBES, INC. 1. X The applicant is hereby notified that the International Search Report has been established and is transmitted herewith. Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46): The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet. Where? Directly to the International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Fascimile No.: (41-22) 740.14.35 For more detailed instructions, see the notes on the accompanying sheet. The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that: the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices. no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made. 4. Further action(s): The applicant is reminded of the following: Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication. Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later). Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Authorized officer

Bruno Danti

Form PCT/ISA/220 (July 1998)

NL-2280 HV Rijswijk

Fax: (+31-70) 340-3016

Name and mailing address of the International Searching Authority

Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,

European Patent Office, P.B. 5818 Patentlaan 2

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international pbulication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been its filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are 51]: "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- [Where originally there were 15 claims and after amendment of all claims there are 11]: "Claims 1 to 15 replaced by amended claims 1 to 11."
- [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
 "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
 "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- [Where various kinds of amendments are made]:
 "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference FOR FURTHER see Notification of Transmittal of International Search Form PCT/ISA/220) as well as, where applicable, item					
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)			
PCT/US 01/48675	14/12/2001	15/12/2000			
Applicant		I			
BOSTON PROBES, INC.	*				
This International Search Report has beer according to Article 18. A copy is being tra	n prepared by this International Searching Auth	ority and is transmitted to the applicant			
This International Search Report consists It is also accompanied by	of a total of sheets. a copy of each prior art document cited in this	report.			
Basis of the report					
 a. With regard to the language, the i language in which it was filed, unle 	nternational search was carried out on the bas ess otherwise indicated under this item.	is of the international application in the			
Additionty (Nule 23.1(D)).	as carried out on the basis of a translation of th				
mas carried out ou the pasis of the	d/or amino acid sequence disclosed in the interpretation in the sequence listing: nal application in written form.	ernational application, the international search			
	national application in computer readable form				
furnished subsequently to	this Authority in written form.				
	this Authority in computer readble form.				
international application as	sequently furnished written sequence listing do filed has been furnished.	es not go beyond the disclosure in the			
the statement that the infor furnished	mation recorded in computer readable form is	identical to the written sequence listing has been			
	d unsearchable (See Box I).				
3. Unity of invention is lack	ing (see Box II).				
4. With regard to the title,					
the text is approved as sub					
the text has been establish METHODS FOR DETERMINING	ed by this Authority to read as follows:				
METHODS FOR DETERMINING	G ORGANISMS				
5. With regard to the abstract,		•			
X the text is approved as sub	mitted by the applicant.				
the text has been established	ed, according to Rule 38.2(b), by this Authority date of mailing of this international search repo	as it appears in Box III. The applicant may, rt, submit comments to this Authority.			
6. The figure of the drawings to be publis					
as suggested by the applica		X None of the figures.			
because the applicant failed because this figure better c		•			
	manaciones the hiveithout.				

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C12Q1/68 G01N33/569

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7-601N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS

C. DOCUMENTS	CONSIDERED	TO BE	RELEVANT
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Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Α	STENDER H ET AL: "I-124. SIMULTANEOUS IDENTIFICATION AND ENUMERATION OF MICROORGANISMS BY FILTER-BASED IN SITU HYBRIDIZATION USING ENZYME-LABELED PEPTIDE NUCLEIC ACID PROBES" ABSTRACTS OF THE GENERAL MEETING OF THE AMERICAN SOCIETY FOR MICROBIOLOGY, AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON, US, Vol. 100, 21 May 2000 (2000-05-21), page 408 XP000956166	1-20
X	ISSN: 0067-2777 abstract	21

X Further documents are listed in the continuation of box C	L		LX	runner documents are listed in the	continuation of box C	,
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X Patent family members are listed in annex.

° Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- 'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed
- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Date of mailing of the international search report

"&" document member of the same patent family

Date of the actual completion of the international search

27 January 2003 14/02/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016 Authorized officer

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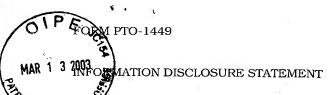
Category °	citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
J-·,	The state of the s	Ticlevant to Claim No.
A X	STENDER H ET AL: "P-26. A NEW MOLECULAR METHOD FOR SIMULTANEOUS IDENTIFICATION AND ENUMERATION OF BRETTANOMYCES IN WINE" ABSTRACTS OF THE GENERAL MEETING OF THE AMERICAN SOCIETY FOR MICROBIOLOGY, AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON, US, VOl. 99, 31 May 1999 (1999-05-31), page 516 XP000952544 ISSN: 0067-2777	1-20
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A *	PLUSKAL M ET AL: "PEPTIDE NUCLEIC ACID PROBES AND THEIR APPLICATION IN DNA AND RNA BLOT HYBRIDIZATION ANALYSIS" FASEB JOURNAL, FED. OF AMERICAN SOC. FOR EXPERIMENTAL BIOLOGY, BETHESDA, MD, US, vol. 8, no. 7, 21 May 1994 (1994-05-21), page A1264 XP000601669 ISSN: 0892-6638 abstract	1-21
P,X *	PERRY-O'KEEFE HEATHER ET AL: "Identification of indicator microorganisms using a standardized PNA FISH method." JOURNAL OF MICROBIOLOGICAL METHODS, vol. 47, no. 3, December 2001 (2001-12), pages 281-292, XP002228739 ISSN: 0167-7012 page 283 -page 284	1-21
Ρ, Χ	STENDER HENRIK ET AL: "Combination of ATP-bioluminescence and PNA probes allows rapid total counts and identification of specific microorganisms in mixed populations." JOURNAL OF MICROBIOLOGICAL METHODS, vol. 46, no. 1, 2001, pages 69-75, XP002228740 ISSN: 0167-7012 page 70 -page 71	1-21
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Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	PC1/03 0	1/ 400/3
Category °			
ratedork .	Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.
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	LUK J M C ET AL: "RAPID AND SENSITIVE DETECTION OF SALMONELLA (0: 6,7) BY IMMUNOMAGNETIC MONOCLONAL ANTIBODY-BASED ASSAYS" JOURNAL OF IMMUNOLOGICAL METHODS, ELSEVIER SCIENCE PUBLISHERS B.V., AMSTERDAM, NL, vol. 137, no. 1, 1991, pages 1-8, XP000566449 ISSN: 0022-1759 abstract		1-21
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Information o	n patent famil	v members
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PCT/US 01/48675

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ATTY. DOCKET NO.: BP0003-US

APPLICANT: O'Keefe et al. SERIAL NO.: 10/017,445

FILING DATE: December 14, 2001

GROUP: 1645

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EXAM		DOCUMENT				SUB	FILING I	λατε ie		
. INIT.		NUMBER	DATE	NAME	CLASS	CLASS	APPROP			
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	AD	5,623,049	April 22, 1997	Löbberding et al.	530	300	Sep. 6, 1			
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